MAY 1 9 2000

CooperVision
711 North Road
Scottsville, New York 14546
(716) 385-6810
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510(k) Summary K001098

SUBMITTER:

Submitted on Behalf of:

Company Name:	Aspect Vision Care, Ltd.
Address:	Unit 2, South Point Hamble SO3 4RF Southampton UK
Phone:	011 44 1703 605200
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CONTACT PERSON: Bonnie Tsymbal

Company Name:	CooperVision, Inc.
Address:	711 North Road Scottsville, NY 14546
Phone:	(716) 264-3210
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DATE SUMMARY PREPARED: March 31, 2000

TRADE NAME: Frequency Colors, Frequency Aspheric Colors and Frequency Toric Colors (methafilcon A) Soft (hydrophilic) Contact Lens

COMMON NAME: Contact Lens

SUBSTANTIALLY EQUIVALENT TO:

The Frequency Colors, Frequency Aspheric Colors and Frequency Toric Colors (methafilcon A) Soft (hydrophilic) Contact Lens for daily wear manufactured by Aspect Vision Care, Ltd. is equivalent to the Frequency 55 (methafilcon A) Soft (hydrophilic) Contact Lens for daily wear (K971164) currently manufactured by Aspect Vision Care. This lens is currently being marketed in the United States by CooperVision, Inc.

The Frequency Colors, Frequency Aspheric Colors and Frequency Toric Colors (methafilcon A) Soft (hydrophilic) Contact Lens and the Fantasy, Natural, Brilliance, Glamour and Crazy lenses manufactured by CL-Tinters (methafilcon A) Soft (hydrophilic) Contact Lens (K982774) are substantially equivalent. Aspect Vision Care, currently provides CL-Tinters with the dry methafilcon A base lens for tinting. Because this methafilcon A base lens is produced at the same manufacturing facility as the Frequency 55 and Frequency Colors, the physical, optical, and chemical properties are the same.

K 001090

The Frequency Colors, Frequency Aspheric Colors and Frequency Toric Colors, the Frequency 55 and the opaque lens from CL-Tinters are all in the Lens Group 4, high water ionic polymer as established by the FDA and located in the Guidance Document for Daily Wear Contact Lenses, Revised Edition May 1994.

DESCRIPTION of the DEVICE:

Frequency Colors and Frequency Aspheric Colors (methafilcon A) Soft (hydrophilic) Contact Lenses are available as spherical lenses. Frequency Toric Colors (methafilcon A) Soft (hydrophilic) Contact Lenses are available as astigmatic (toric) lenses. The lens material, methafilcon A, is a random copolymer of hydroxyethylmethacrylate and methacrylic acid. The lenses are made by modifying the uncolored methafilcon A lens by affixing a colored pigment on that portion of the front surface that corresponds to the iris. The colored pigments consist of carbazole violet, chromium oxide green, dihydrodinaphto brown, dihydrodioxo yellow, phthalocyanine green, iron oxide red, iron oxide brown, iron oxide black, phthalocyanine blue, and titanium oxide.

	Frequency Colors	**CL-Tinters Opaque**	**Frequency 55**
Material	methafilcon A	equivalent	equivalent
Material Classification	Hydrophilic Lens Group 4	equivalent	equivalent
Indication for Use	Daily Wear myopia, hyperopia and astigmatism	Daily Wear myopia and hyperopia	Daily Wear myopia and hyperopia
Water Content	55%	equivalent	equivalent
Light Transmittance	>96%	equivalent	equivalent
Dk (35°)	15.5×10^{-11}	equivalent	equivalent
Index of Refraction	1.41	equivalent	equivalent
Powers	-20.00 to +20.00	equivalent	-8.00 to +8.00
Pigments	carbazole violet, chromium oxide green, dihydrodinaphto brown, dihydrodioxo yellow, phthalocyanine green, iron oxide red, iron oxide brown, iron oxide black, phthalocyanine blue, and titanium oxide.	When produced with a handling tint, the color additive Blue No. 4 is used.	carbazole violet, chromium oxide green, dihydrodinaphto brown, dihydrodioxo yellow, phthalocyanine green, iron oxide red, iron oxide brown, iron oxide black, phthalocyanine blue, and titanium oxide.
Tint Process	Pad Printing, Post lens forming	In-Monomer Tint	Pad Printing, Post lens forming
Manufacturing Method	Molded	equivalent	equivalent

INDICATIONS FOR USE:

The Frequency Colors and Frequency Aspheric Colors (methafilcon A) Soft (hydrophilic) Contact Lens are indicated for daily wear to enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for the management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia.

K001090

Frequency Toric Colors are indicated for daily wear to enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for the management of conditions such as corneal, iris or lens abnormalities . The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons with non-diseased eyes. The lenses may be worn by persons who have astigmatism of 12.00 diopters or less or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia.

If the lenses are to be prescribed for Frequent/Planned Replacement Wear, they should be cleaned, rinsed and disinfected each time they are removed from the eye and discarded after the recommended wearing period prescribed by the eye care practitioner. Lenses prescribed for Disposable Wear, the lenses should be discarded daily at removal.

The Frequency Colors, Frequency Aspheric Colors and Frequency Toric Colors are to be disinfected using a chemical (not heat) disinfection system, including hydrogen peroxide.

This is the same indication as the predicate device. An Indications for Use Statement is located in Attachment I.

The lenses are to be disinfected using either a thermal (heat) or chemical (not heat), including hydrogen peroxide.

PRECLINICAL INFORMATION:

The results of toxicology testing, including Ocular Irritation, Cytotoxicity and Systemic Injection, have demonstrated that the subject lens is non-toxic. A leachability study was conducted to assess the color fastness of the pigments used to tint the Frequency Colors, Frequency Aspheric Colors and Frequency Toric Colors (methafilcon A) Soft (hydrophilic) Contact Lens. The study demonstrates that after two weeks of extraction at 37° C in saline, undetectable levels (≤1 ppm) of dye were observed in the extraction solution.

The physical, optical and chemical properties of the subject Frequency Colors, Frequency Aspheric Colors and Frequency Toric Colors (methafilcon A) Soft (hydrophilic) Contact Lens are equivalent to those of the opaque (methafilcon A) Soft (hydrophilic) Contact Lens from CL Tinters since the base methafilcon a lens provided to CL Tinters is the same as that used for Frequency 55 and the Frequency Colors product line.

CONCLUSION:

The information provided in this 510(k) establishes that the Frequency Colors, Frequency Aspheric Colors and Frequency Toric Colors (methafilcon A) Soft (hydrophilic) for Daily Wear is equivalent in optical, chemical and physical properties of the predicate device and does not raise any questions of safety and effectiveness. Therefore, the device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 9 2000

Ms. Bonnie Tsymbal
Manager, Regulatory Affairs
CooperVision, Inc.
711 North Road
Scottsville, NY 14546

Re: K001090
Trade Name: Frequency Colors, Frequency Aspheric Colors and Frequency Toric Colors (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear
Regulatory Class: II
Product Code: 86 LPL
Dated: May 10, 2000
Received: May 11, 2000

Dear Ms. Tsymbal:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Indication for Use Statement

510(k) Number: K001090

Device Name: Frequency Colors
Frequency Aspheric Colors
Frequency Toric Colors

Indication for Use:

1. Frequency Colors and Frequency Aspheric Colors are indicated for daily wear to enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for the management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia.

2. Frequency Toric Colors lenses are indicated for daily wear to enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for the management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who have astigmatism of 12.00 diopters or less or for occlusive therapy for conditions such as diplopia, amblyopia an extreme photophobia.

Frequent/Planned Replacement Wear

When prescribed for Frequent/Planned Replacement Wear, the Frequency Colors, Frequency Aspheric Colors and Frequency Toric Colors lenses are to be cleaned, rinsed and disinfected each time they are removed from the eye and discarded after the recommended wearing period prescribed by the eye care practitioner.

Disposable Wear

When prescribed for Disposable Wear, the wearing time prescribed by the eye care practitioner is for daily wear (single use). Patients should be instructed to discard the lenses at each removal.

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K001090

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)